K131681

510(K) SUMMARY

EyeSeeCam vHIT

Submitter Information:

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Date Summary Prepared	May 22 2013

SEP 0 6 2013

Device Identification:

Trade Name	EyeSeeCam vHIT
Common Name	Vestibular analysis device
Classification Name	Nystagmograph, apparatus, vestibular analysis
Product Code	GWN, LXV
Panel	Neurology / Ear Nose & Throat
Device Class	Class II (According to 21 CFR 882.1460)

Predicate Devices:

Predicate Device	VORTEQ/VISUALEYES
Manufacturer	Micromedical Technologies
510(k) No.	K891008 / K964325
Date Cleared	05/31/1989 / 07/15/1997

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Device Description

vHIT is intended to be used as a quick and objective measurement of the vestibular ocular reflex (VOR) in response to head movements in the natural range of daily motions. The results will yield immediate information regarding side-specific vestibular function. EyeSeeCam vHIT allows the healthcare professional to efficiently assess the "dizzy" patient and quickly decide if the dizziness the patient is experiencing is related to a vestibular disorder.

The EyeSeeCam vHIT system consists of a head mounted goggle/mask, a camera unit with calibration laser and a software application running on a standard PC.

The vHIT goggle generally has one camera (monocular) fixed at the top side(s) of the mask. The camera is held in place mechanically with a spherical ball-and-socket joint. The vHIT goggle has support for camera position-for the left and for the right eye. Therefore the camera is interchangeable between the left and right eyes.

The vHIT goggle supports the camera that is used to record the eye images. This constitutes the major component of the vHIT system.

The USB camera uses infrared light (IR), which is not visible to the naked eye. The IR illumination enables sessions to be performed in complete darkness.

The vHIT goggle has dichroic mirrors that allow visible light to pass through and infra red light to be reflected towards the cameras.

A calibration laser is placed in the center of the goggle. This is used for camera / pupil calibration before testing.

The complete system is operated from a standard PC/Laptop via a standard USB connection. The PC application software controls the camera recordings and shows the results of the tests.

EyeSeeCam utilizes an inertial measurement unit (IMU) which is an accelerometer and gyroscope combined. The IMU is contained inside the camera unit. The camera housing is attached to a light weight goggle. The camera records eye movements and the IMU records an electronic waveform that is proportional to head angular velocity (deg/sec).

Indications for Use

The EyeSeeCam vHIT is designed to provide information on the performance of the vestibular ocular reflex (VOR) by providing objective measures of eye-velocity response to head-velocity stimulus, showing the VOR gain in the plane of rotation of the head.

Intended operator

The system is to be used by trained personnel only such as audiologists, ENT surgeons, neurologists, hearing healthcare professionals or personnel with a similar level of education.

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Technological Characteristics

The EyeSeeCam vHIT system consists of a head mounted goggle/mask, a camera unit with calibration laser and a software application running on a standard PC.

Nonclinical tests summary

Design verification and validation were performed according to current standards for medical device safety and EMC. The device was found in compliance with current standards

Clinical tests

Clinical testing compared test results between the EyeSeeCam vHIT and the Predicate Device. The results showed compliance and substantial equivalence between the two instruments.

Conclusion

We trust that the verification and validation activities show substantial equivalence with the substantial equivalent device and that the EyeSeeCam vHIT is safe and effective for its claimed purpose.

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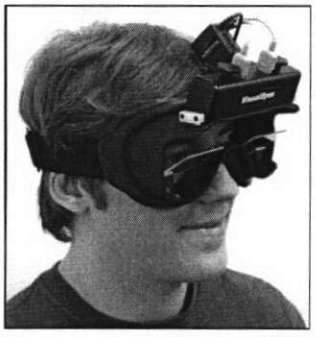
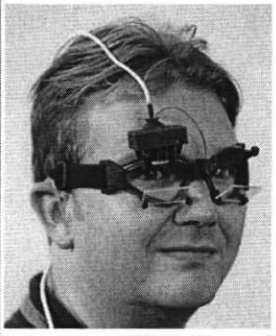
Comparison table

Description	Micromedical Technologies VORTEQ /VISUALEYES	EyeSeeCam vHIT	Equivalence
Indications for use	VORTEQ is designed to provide information about the Vestibular Ocular Reflex (VOR) in patients with dizziness or balance problems	The EyeSeeCam vHIT is designed to provide information on the performance of the vestibular ocular reflex (VOR) by providing objective measures of eye-velocity response to head-velocity stimulus, showing the VOR gain in the plane of rotation of the head.	Similar Please refer to Discussion, Similarities in indications for use below
Technology General	VORTEQ utilizes an angular velocity sensor mounted directly to the VisualEyes™ FireWire Binocular Goggles. With the VisualEyes™ Monocular Goggles, the angular velocity sensor is attached to the back of the goggle headband for VORTEQ testing. This solid state sensor produces an electronic waveform that is proportional to head angular velocity (deg/sec).	**EyeSeeCam** utilizes an inertial measurement unit (IMU) which is an accelerometer and gyroscope combined. The IMU is contained inside the camera housing. The camera housing is attached to a light weight goggle. The camera records eye movements and the IMU records an electronic waveform that is proportional to head angular velocity (deg/sec).	Similar See following technical comparison and photo below
Technology Photo			Similar See following technological comparison
Technology (Interface)	Firewire® (IEEE-1394a)	USB	Similar Two similar communication protocols/technologies
Technology (Mono/Dual Cameras)	Monocular or binocular	Monocular camera, interchangeable between left and right eyes	Similar One or two cameras for VORTEQ while only one

Description	Micromedical Technologies VORTEQ /VISUALEYES	EyeSeeCam vHIT	Equivalence
			for EyeSeeCam
Technology (Goggle)	Comfortable fit, Molded vinyl, fits adult faces only (aprx 400 grams)	Snug fit, Molded cleanable silicone, Fits pediatric and adult faces (aprx 60 grams)	Similar Based on description
(Technology) Calibration	Non head-mounted LED (E.g. a Digital Lightbar)	Head mount laser with 5 point calibration	Similar We ascertain that that the calibration systems are substantially equivalent with the same purpose to adjust the camera recordings to the eye positions. Both technologies measure eye movements to projected dot patterns, (MMT uses a light bar and ESC uses a laser on the goggle).
Technology (Sample rate)	250Hz	220Hz	Similar The sample rate deviation is appraised not to influence the measurements.
Technology (Head tracking sensor)	Gyroscopes with 6 degrees of freedom	Inertial Measurement Unit (IMU) gyroscope with 6 degrees of freedom	Same
Technology (Gain)	Instantaneous gain measured at 45 ms with selectable slide bar to change to any value, e.g. 40, 60, 80 ms	Instantaneous gain at 40, 60, and 80 ms like a scleral coil search method	Similar EyeSeeCam has tree fixed values like scleral coil while VORTEQ has a range also covering the same values.
Technology (Data Analysis)	V-Plot, Gain Plot	Velocity Regression Plot, Gain Plot	Same
Compliance Standards	Safety: IEC 60601-1, UL 60601, CAN/CSA-C22.2 No. 601.1-M90, Class II, Type B, IPXO, EMC: IEC 60601-1-2 Laser: IEC 62471-1, IEC 60825-1	Safety: IEC60601-1, ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601.1:08, Class II, Type B, IPXO, EMC: IEC 60601-1-2 Laser: IEC 62471-1, IEC 60825-1	Same

Discussion, Similarities in Indications for use
The vestibulo-ocular reflex (VOR) is a reflex eye movement that stabilizes images on the retina during head movement by producing an eye movement in the direction opposite to head movement, thus preserving the image on the center of the visual field. For example, when the head moves to the right, the eyes move to the left and when the head moves up the eyes move down. The indication for use for EyeSeeCam includes a slightly more detailed description of the same head impulse test procedure used to measure the VOR - including the canal tested is in the direction of the motion of the head movement - this includes both vertical and horizontal VOR tests. The VOR test described by VORTEQ is certainly capable of testing both horizontal and vertical canals, it just doesn't specify which canals are tested in the intended use statement.

Summary of similarities
We appraise that slightly different technologies have been used in the two products (e.g. USB or Firewire / one or two cameras) but the functionality is ascertained to have the same purpose.

Discussion of differences
We did not find any essential or major differences between the two devices.

Verification and validation summary
We have verified EMC, safety and software performance. We have performed clinical comparisons between the EyeSeeCam and VORTEQ. We have reviewed the literature for articles about vestibular testing with vHIT. All these activities, testing and validation show that EyeSeeCam vHIT performs as specified and is safe and effective.

Conclusion
We have compared key issues for the EyeSeeCam vHIT and the predicate device VORTEQ. We have performed a comparison validation between EyeSeeCam and VORTEQ. All similarities and differences have been discussed. We trust that the results of these comparisons demonstrate that the EyeSeeCam vHIT is substantially equivalent to the marketed predicate device.

Any deviations between EyeSeeCam vHIT and predicate devices are appraised to have no adverse affect on the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

Interacoustics A/S
c/o Mr. Erik Nielsen
Director, Quality and Regulatory Affairs
Drejervaenget 8
Assens, Denmark DK-5610

Re: K131681
Trade/Device Name: EyeSeeCam vHIT
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: June 10, 2013
Received: June 10, 2013

Dear Mr. Nielsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for: Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Applicant: Interacoustics A/S

510(k) Number (if known): K131681

Device Name: EyeSeeCam - vHIT

Indications for Use:
The EyeSeeCam vHIT is designed to provide information on the performance of the vestibular ocular reflex (VOR) by providing objective measures of eye-velocity response to head-velocity stimulus, showing the VOR gain in the plane of rotation of the head.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Eric A. Mann -S

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